USDA Plant Variety Protection Office (PVPO) Ogden Room of the Hyatt Regency Chicago Hotel 151 East Wacker Drive Chicago, IL

Board Members attending (with affiliation):

June Blalock; Agricultural Research Service Collaborator

Leticia Cabrera; Northwest Missouri State University

Joonhyung Cho; University of North Carolina at Chapel Hill

Harry Collins; Mississippi Farmer

Danielle Conway; University of Hawaii at Manoa Jonathan Egilla; Lincoln University in Missouri

Patrick Kole; Idaho Potato Commission Stevan Madjarac; Monsanto Company

Corinne Marshall; Sakata Seed America, Inc. Salomon Montano; New Mexico Farmer;

Dana Rewoldt; Lawyer

Wendell Shauman; Illinois Farmer;

Absent: Hezekiah Gibson; United Farmers USA/Gibson Farm

USDA staff:

Ruihong Guo, Deputy Administrator, USDA/Agricultural Marketing Service (AMS)/Science and Technology Program

Sharlene Deskins, Attorney, Office of General Counsel (OGC)

Paul Zankowski; Commissioner PVPO

Jeff Haynes, Deputy Commissioner, PVPO

Others Attending:

Fred Ashaw, Monsanto

Marymar Butruille, Monsanto

Marc Cool, DuPont Pioneer

Martin Ekvad, Community Plant Variety Office (CPVO)

Shawn Kaeppler, University of Wisconsin

Paul Nelson, Monsanto

John Schoenecker, HM-Clause

Fawad Shah, AMS Seed Regulatory and Testing Branch

Bernice Slutsky, American Seed Trade Association (ASTA)

Stephen Smith, DuPont Pioneer

Marty Turner, STEP Ltd.

Ann Marie Thro, USDA

Call to Order, Introductions, and Opening Remarks

A moment of silence was held in observance of the passing of Board member Larry Teuber.

The meeting agenda was adopted.

The PVPO explained the function of the Board according to the PVP Act to 1) provide guidance on PVP regulations, 2) make advisory decisions on all appeals to the Secretary, and 3) advise the Secretary on questions regarding declaring varieties open for public use.

There were no appeals to the Secretary

PVP 2014 Accomplishments and Finances

In fiscal year (FY) 2014 the PVPO processed/examined 818 PVP applications reducing its application inventory from 642 to 347 applications and decreasing the average processing time from 2.78 years (in 2013) to 2.43 years. The PVPO received 523 incoming applications in FY 2014, which was a 7% increase over the 488 applications received in FY 2013.

The PVPO Trust Fund began FY 2014 at \$3.2 million; during the year there was \$2.9 million in revenue and \$2.2 million in expenses which resulted in a year end trust fund balance of \$3.9 million (equivalent to 18.4 month operating reserve). The Board asked what was the minimum operating reserve – it's 4-5 months. Expense saving resulted from the 2012 PVPO move (no rent), staff reductions, and PVPO staff telework options.

PVP 2015 Performance Plan

In FY 2015 the PVPO plans to process 500+ PVP applications, maintain the inventory below 500 applications, and reduce the average PVP application processing time from 2.3 years to 2.0 years. The Board suggested that it may be useful to look at the median processing time, which will probably be lower and also separate out the time that applicants take to respond. The PVPO also plans to take action on all FY 2012 and 50% of FY 2013 applications. The PVPO will continue working toward increasing cooperation in PVP examination with the European Union (EU), Canada, and other countries.

In FY 2015 the PVPO plans to increase outreach to the grass/lawn seed and potato industries. The PVPO also plans to increase the PVPO staff's understanding of global

intellectual property issues by enrolling staff in International Union for the Protection of New Varieties of Plants (UPOV) online courses, participate in DUS (distinct, uniform, and stable) field observations by visiting trials and viewing grow out studies, increasing staff understanding of molecular marker usage for PVP through local and online training, and enrolling staff in change management classes.

Electronic PVP (ePVP) Update

The PVPO planned to launch its ePVP system in April 2014 with the goal of replacing the STAR Database System with Microsoft Customer Relationship Management (CRM) software system. The official launch was delayed due to migration problems associated with multiple occurrence data fields and non-PVP variety reference data. Currently the launch is planned for May 1, 2015 with a limited number of crops. Other crops will be added later until all are migrated and can be examined using CRM.

The system was developed with an Agile approach with 3 week sprints (mini projects) which produced a workable subsection of software that could be tested. The system incorporates an external user portal for entering applications with PVP payments made using pay.gov. The CRM software will be used by the PVP staff to examine applications and make a final recommendation for PVP certification. Beta testing of the software is ongoing, using mostly internal users and several external testers. Additional external testers will be incorporated into the next series of software testing beginning in January 2015.

Problems occurred with the migration of legacy data from STAR since each crop had separate databases requiring different migration approaches. Also there were problems with multiple occurrence fields and non-PVP reference data that didn't migrate.

The next steps for the ePVP system will be

- 1. Complete testing to assure that the 29 crops have been migrated successfully from STAR to the ePVP System.
- 2. Work out a method to correct the remaining 26 crop databases to correctly migrate them from STAR to the ePVP System.
- Continue using both (STAR and ePVP) systems simultaneously until all crops are migrated.

The official ePVP launch is planned for May 1, 2015 for the 29 crops and will be announced with a Federal Register notice and press release. The crops that will be available at the ePVP launch include soybean, pea, garden bean, dry bean/field bean, sweet pea, lima bean, chick pea, peanut, pepper, aster, broccoli, spinach, lentil, mustard, radish, stocks, guayule, artichoke, lobelia, cucumber, snap dragon, calendula,

daisy, buffalo grass, peach, turnip, asparagus, cabbage, lupine, and all other small volume crops, or crops without an existing STAR database. The 26 crops that will require more data migration work for ePVP include fine and hard fescue, tomato, bentgrass, squash/pumpkin, muskmelon, zinnia, carrot, triticale, pakchoi, rape seed, watermelon, onion, vinca, corn, wheat, cotton, lettuce, ryegrass, potato, tall fescue, bluegrass, barley, sorghum, rice and oat. These crops will be added one by one as the data migration issues are resolved. Resolution of migration problems will involve either fixing the data in STAR or migration to CRM with a script that solves these problems. Also capabilities such as bulk uploading of applications will be added later under a separate development contract.

The Board asked how big of a challenge will it be to migrate corn data —it will require a longer time, due to the complexity of the data, reference varieties, and multiple occurring fields.

The PVPO is still working under the same \$2.1 million budget for the ePVP system with the contractor, and is under budget by \$300,000, so there is flexibility to add more features. An observer mentioned that under the Agile approach that was used to develop the ePVP system everything is not mapped out as needed, instead there is testing and development resulting in what is needed versus what was envisioned.

The PVPO also mentioned that the US has assisted with the requirements of the UPOV Electronic Application System based on the lessons learned from ePVP development.

<u>Update on UPOV International System of Cooperation (ISC)</u>

Steven Smith made a presentation on the concept of an ISC that was developed with input from the International Community of Breeders of Asexually Reproduced Ornamental and Fruit Varieties (CIOPORA), CropLife International, and the International Seed Federation (ISF). This idea was generated after a questionnaire from ISF was sent to its members asking about their view on global PVP systems. ISF looked at the Patent Cooperation Treaty (PCT) system for guidance to develop the ISC concept. The presentation reiterated that plant breeding and the production/trade of propagating/harvested material has become much more global.

The ISF survey found 1) gaps in effective global PVP regimes that can limit plant breeding and provide opportunities for misappropriation; 2) lack of consistency globally in the quality of reference collections, capabilities, and the resources to do DUS analyses; and 3) a lack of consistency in many aspects of PVP administrative procedures.

The ISC would be a means to complement national PVP systems in that it would 1) use a standard application form using the language of choice that would be built on an electronic application form, 2) standardize the application fee, 3) allow one application to serve the requirements of several countries, and 4) provide a standard check of novelty.

Under ISC - UPOV members would share testing responsibilities with a maximum advantage of reference collections to encourage centers of excellence in DUS testing to be developed and promote variety descriptions that better match the final product. The ISC would promote a global means for consistent high quality DUS examination and work toward UPOV developing an accreditation system. The benefits of ISC include 1) streamlining the application filing and processing, 2) avoiding duplication and inconsistencies, 3) applications would be easier and less time consuming for applicants, 4) reduction in time and costs in application preparation/filing, and 5) clarification of novelty.

ISC plant breeders in all UPOV member countries would have access to the DUS examinations. There would be increased incentives for more breeders to apply for and obtain PVPs with an increase in the overall number of PVP applications due to simpler and cost-effective application process. ISC could also encourage companies/breeders to invest more in plant breeding and variety development.

ISC could increase the number of crops for which UPOV members can provide cost effective DUS examinations. Sharing of DUS testing will lead to centers of excellence on a crop by crop basis which could provide higher quality under a simplified process coupled with more global coverage of PVP which may encourage additional countries to join UPOV.

The ISC concept was presented to the October 2014 UPOV Consultative Committee (CC) - both the EU and U.S. strongly supported the ISC concept and several other countries showed general support but had questions on the details. The CC requested the UPOV Office to prepare a document to clarify the issues raised and possible ways forward for consideration by the CC at the March 2015 session.

The Board asked about the different ways that DUS testing is done in each country and who would pay for it. The Board commented that there may be a competitive approach to file for PVP in the country that charges the least fees. The Board also commented that in some countries, the DUS testing may take 2+ years and 4+ years for fruits/trees and that it may require a longer overall time to obtain PVP than in the U.S. It was

further explained that under an ISC - basic information might be entered into an ISC application but individual countries might still conduct their own DUS tests.

The Board asked if the question of public interest uses was discussed during the UPOV ISC presentation because it would be important for the African countries – it was not. The Board asked if the PVPO was linked to the US Patent Office (PTO) regarding the ISC –PTO is aware of the ISC, but their criteria for issuing patents is different from DUS. The Board recommended that the PVPO look into a process that can incorporate both the U.S. and EU type systems to work in cooperation perhaps via the ISC.

<u>Update on UPOV Electronic Application System (EAS)</u>

Stevan Madjarac presented an update on UPOV's EAS efforts. UPOV initiated discussion on an EAS in 2011 since breeders have expressed interest in an EAS system since 2007. Initial EAS planning involved UPOV, the World Intellectual Property Organization (WIPO), the CPVO, and breeders to provide a good basis for a system that would have gains in efficiency and effectiveness.

The UPOV electronic form would enable data to be transferred to participating UPOV members in Word, Excel, PDF and XML formats. The UPOV member would decide in what format(s) to accept data, and in the case of XML format, a standard format would be developed, based on WIPO's standard ST96.

The UPOV prototype EAS form would include a dashboard with edit / delete/ submit options, an administrative interface, an import facility, and an XML export facility. It would not include a payment system or be translated into different languages. Out of 72 UPOV members, 20 including the U.S. PVPO have been participating in the EAS discussions. UPOV members will provide feedback and suggestions, in order to maximize practical applicability for the U.S. and other countries.

The Board wanted to know if the UPOV EAS will be different from the U.S.'s ePVP –the system will be similar but with the EAS being more global, also the U.S. can incorporate UPOV EAS components into its ePVP system. UPOV is asking the U.S. and other countries to actively participate in the development of the EAS. The basic PVP application questions are mostly the same between UPOV members, however the UPOV technical questionnaires may pose some challenges depending on each country's requirements. The UPOV system will act more as a conduit to send applications to each country. UPOV developed the prototype form with questions that are common between all countries and is adding the country specific questions as

needed. The Board asked if applicants would pay fees to each country in the EAS – fees aren't included in the current EAS prototype.

Summary of the Seed Association of the Americas (SAA) PVP Workshop

The first workshop occurred in Sao Paulo, Brazil, November 3-4, 2014. Participants were from Canada, United States, Mexico, Chile, Paraguay, Brazil, Argentina, Uruguay, as well as the UPOV Office. The U.S. PVPO was represented by PVP Examiner Brian Ikenberry, who made a presentation on ePVP and the U.S. database system for variety names.

The objectives of the workshop were to

- Improve the common understanding of PVP in the region
- Exchange information on the processes for protection of new varieties of plants
- Identify opportunities for cooperation among National PVP Offices
- Identify opportunities to better communicate the benefits of Plant Breeders Rights

The key outcomes and future steps are:

- To highlight top priorities, participants agreed that the following items rank high:
 - Technical and policy aspects of using supplementary molecular marker information in distinguishing soybean varieties
 - Development of electronic forms for PVP filing
 - Coordinating product naming across the region with an emphasis on soybeans
- Participants recognized the need to hold regular meetings in the future
- It would be a priority for the US PVP Office to continue participating and providing leadership in strengthening regional effort for protecting varieties.

The PVPO discussed that attending unscheduled meetings is a challenge due to funding and because the PVPO annual travel/meeting plan is established and approved in August of the prior year. The Board mentioned that American Seed Trade Association (ASTA) often received USDA cooperator funds for these types of meetings. The Board recommended that the PVPO should continue participating in SAA meetings.

Molecular Markers in the Context of PVP

An overview of the use of molecular markers was presented by Professor Shawn Kaeppler and focused on the 1) utility of genotyping to distinguish varieties and markers proven to affect phenotype versus anonymous markers. Molecular markers can be developed from sequenced RNA as well as other methods. In maize 453,000 Single

Nucleotide Polymorphism (SNP) markers were used in a genome-wide association study (GWAS) to show how similar or dissimilar varieties are on a molecular scale.

The relationship between maize lines was compared using markers – for example stiff stalk, non-stiff stalk, tropical, versus popcorn. Traits such as ear length, kernel row number, and days to flowering can be used to distinguish maize varieties as well as with markers. Regions of DNA can be used to clearly distinguish one variety from another. Lines can be equally genetically distant from each other but have very different marker profiles.

In summary markers can provide unambiguous distinctness data among genotypes with similar phenotypes. Deep marker coverage is affordable with techniques like RNAseq and can allow SNP discovery in species with limited genomic resources. Affordable platforms can provide comprehensive information on hundreds to thousands of SNPs such as Illumina Infinium, Sequenom, and Kaspar.

Types of molecular technology can include

- Isozyme using Starch Gel Electrophoresis
- RFLP Restriction Fragment Length Polymorphism using DNA Gel Blot
- SSR -- Simple Sequence Repeat (a.k.a. microsatellite) using PCR / Gel electrophoresis
- RAPD -- Randomly Amplified Polymorphic DNA using PCR / Gel electrophoresis
- AFLP Amplified Fragment Length Polymorphism using Adapter ligation/ PCR / Gel electrophoresis
- SNP Single Nucleotide Polymorphism
 - CAPS Cleaved Amplified Polymorphic Site using PCR / restriction digest / gel electrophoresis
 - SSCP Single Strand Conformational polymorphism using PCR / Denaturing Gel Electrophoresis

The Board asked whether it is important that markers are linked or causal to a phenotype? – no, it shouldn't matter toward differentiating varieties. There are few phenotypes with direct relationship to markers. Most, even "simple", traits are controlled primarily by many genes with small effects. Anonymous markers can provide clear distinction between varieties regardless of known effect on phenotype. The Board asked whether the "effect or the outcome" allowable under PVP - PVP regulations were most likely based on genotype instead of phenotype. It was discussed that traits such as yield were not acceptable for PVP distinctness, but that is often the most important trait of a variety. There was a discussion that during crime scene investigation matches

of DNA are valid as evidence without any regards to expression of that DNA – i.e. hair color, eye color, etc.

The Board indicated that a plant's phenotype is affected by the environment - so that a variety grown in the moist tropics looks much different when grown in the desert. The Board asked, would the DNA fingerprint be different from a plant grown in the moist tropics versus one grown in the desert – no, the fingerprint would remain the same even though the variety looked different in different locations.

The Board asked when selections are based on anonymous markers would there be genetic drift over time – it was thought that drift might be possible, but the goal for most selections is phenotype and not genotype. It was concluded that no single marker is able to distinguish a variety, whereas a group of markers can provide distinction.

Seed Innovation and Protection Alliance (SIPA)

James Weatherly, the Executive Director made a presentation about the SIPA – it was incorporated on July 16, 2014 and is owned by ASTA. Program officers are from Enza Zaden, Monsanto, and Bayer Crop Science. SIPA is a member driven organization dedicated to promoting the understanding of the value of seed innovations and the need for protection and enforcement of intellectual property rights that benefit growers, industry associates, consumers and the agricultural community. SIPA's mission is to 1) educate/increase the understanding of innovation's value, and why variety developers need to protect innovation, 2) facilitate and promote the compliance of innovation, 3) establish best practices for members, and 4) promote seed innovation while reducing enforcement issues.

SIPA's mission is relevant to US agriculture, which has over \$200 billion in annual sales. A recent survey showed that the costs in lost revenue for an intellectual property violation is \$300,000 to \$500,000 and can extend into the millions depending on the seed technology.

The guiding principles for SIPA are 1) promoting and encouraging a high standard of business ethics among members and the seed industry as guided by a Code of Conduct; 2) honoring contracts between seed companies, suppliers, and customers involving the use and protection of intellectual property; 3) working to educate members, the industry, growers and the community at large on the benefits of seed innovation rights and the responsibilities of intellectual property owners concerning seeds and traits, including patents, plant variety protection, plant breeders' rights, trademarks, and copyrights; 4) facilitating and promoting enforcement of intellectual property rights for the benefit of members, growers, consumers and the agricultural community; and 5)

commitment to best practices related to the identification, promotion, and protection of seed innovation. SIPA helps customers understand their rights for PVP, utility patents and plant patents. SIPA is not an enforcement organization.

Under SIPA's code of conduct member companies sustain and advance the integrity, honor, and prestige of the seed industry by:

- 1. Complying at all times with the Alliance Antitrust Compliance Policy.
- 2. Understanding and complying with valid and relevant federal and state laws as well as foreign national laws relating to intellectual property rights in seed and seed technologies, including judicial interpretations of such laws.
- 3. Establishing best practices for services related to the protection or enforcement of seed and seed technologies.
- 4. Honoring valid contracts, including but not limited to production, marketing, distribution, or sale of seed, between seed companies, service providers, suppliers, and customers involving the use and protection of intellectual property as well as governing confidentiality and trade secrets.
- 5. Honoring agreements to arbitrate disputes involving the sale of seed, including agreements relating to the use of intellectual property, and abiding by all binding arbitration or judicial decisions thereof.

SIPA is currently divided into a vegetable and flower and field crop, and with the potential of adding other crop divisions in the future. There are different membership levels that cost different amounts. SIPA is trying to reach its members, integrated seed companies, growers and producers, cleaners, brokers, service providers, and consumers with its message. SIPA is planning to identify and develop educational materials; develop best practices related to the identification, promotion, and protection of seed innovation; serve as both a clearinghouse and repository of educational materials; and provide educational workshops directed to integrated seed companies, growers and producers, brokers and dealers, cleaners, and service providers.

SIPA plans to facilitate and promote compliance of intellectual property rights limited to education and investigative services where SIPA serves as an information repository by working with seed treating companies, auditors, investigators, and law enforcement on criminal issues. SIPA plans to provide a mechanism for anonymous reporting of compliance issues. SIPA is not an enforcement agency but instead wants to promote compliance.

The Board asked: what were the top intellectual property protection enforcement issues for the vegetable industry? – protection of lettuce, tomatoes, and beans because their protection was more difficult. The Board asked: what did SIPA consider as the barriers

regarding PVP? – enforcement of PVP and farmer-saved seed were the biggest issues. It was commented that in Europe the farmer-saved seed issue is acceptable because farmers and the seed organization have reached an agreement that if farmer want quality seed they need to pay the breeder a royalty on saved seed.

PVP Regulations and Fee Changes

The PVP regulation changes that were proposed at the December 2013 Board meeting were included:

- 97.5 c PVPO's address change
- 97.5 i accept copies of foreign PVP documentation
- 97.9 changing "shall" to "should"
- 97.20 addition of postmark rule with the proposed text
 - "(d) Applicants shall be considered as having provided a timely response when the U.S. mail postmark date falls within the required response timeframe."
- 97.12 changing "in the order" to "by the order"
- 97.19 change regarding the Official Journal to "Information relating to pending applications shall be published periodically, as determined by the Commissioner to be necessary in the public interest"
- 97.23(d) be deleted
- 97.102, 97.152, 97.156, 97.201(a), 97.400 add the phrase "and payment of the appropriate fee" at the end of these sections
- 97.155 change to allow for electronic signatures or scanned images/faxes of signatures
- 97.175 fees

add a change of owner/representative or change of owner/representative address fee (\$41)

Regulation changes that were proposed for 2014 included:

- 97.5 General Requirements
 - (a) (3) add statement "or the World Trade Organization" before ", shall be entitled"
 - (c) add PVP website instead of postal address
- 97.7 Deposit of Voucher Specimen (d) Time of making an original deposit.

 add "An original deposit of materials for tuber-propagated plants shall be made within three months from the date of the notice of allowance."

The Board asked if the tuber deposit could be made sooner than the notice of allowance date – yes, applicants could deposit tuber sooner.

97.500 Appeal to U.S. Courts

delete and add as follows: "Any applicant dissatisfied with the decision of the Secretary on appeal, may appeal to the U.S. Court of Customs and Patent Appeals or the U.S. Courts of Appeals for the Federal Circuit"

The proposed fee changes were:

1) Sale of PVP DUS report

The current fee for copies of any U.S. PVPO document is \$1.80 per page plus \$1.80 per page for signature. The PVPO in other countries charge UPOV's recommended 350 Swiss Francs (approx. \$358). The PVP regulations would allow this under section 97.175 (s)) "...rates prescribed by the Commissioner, but in no event shall they exceed \$107.00 per employee-hour. Charges also will be made for materials, space, and administrative costs."

The Board asked if the sale of the report was 1) to raise money or 2) to reduce employee time processing time - the posting of the entire certificate and application cost staff time/money compared to limiting the amount of information to post. The Board asked: what was the estimated cost to produce the final report – it might be better to increase the cost per page.

The CPVO indicated that they charge another PVP office the 350 Swiss francs for the purchase of a CPVO report, but provide this information to the variety owner free of charge.

The Board indicated that sometimes it is valuable to submit an application that was submitted to another country's PVP office instead of having a new DUS trial/report done. The Board indicated that there is an institutional cost of providing the PVP report and all the underlying issues of creating the report. The Board noted that the PTO also makes all the information of issued patents publicly available for free.

The Board commented that the PVPO continue to make the PVP report freely available but with a watermark indicating "Unofficial Copy". The CPVO indicated they also do this and distinguish between the unofficial versus the official CPVO reports.

Paper Processing Fee
 The PVPO would add the paper processing fee once ePVP is fully implemented

The PVPO plans to drop the concept of "per-month extension and late fee" that was proposed during the December 2013 PVP Board meeting. The Board commented that some applicants may want to submit poor applications in order to get a longer period of protection due to delays in application processing. The PVP Act allows reducing the period of protection if there is evidence of unnecessary applicant delays (see PVP Act 83(b)(2)).

December 9, 2014

Forms Subcommittee Interim Report

June Blalock provided an update on the Forms Subcommittee - the December 2013 Board recommended the formation of this subcommittee to consider changes to PVP Forms ST-470 and ST-472. During the December 2013 meeting the National Center for Genetic Resources Preservation (NCGRP) indicated that it would provide a disclaimer to seed recipients regarding the patent/intellectual property protection status of seeds they were receiving. The Subcommittee met by teleconference in June 2014 and it reviewed relevant background information, discussed options for changing the forms, agreed on interim recommendations, and prepared a list of questions for USDA Office of General Counsel (OGC). Questions were submitted to AMS and Agricultural Research Service (ARS) OGC in August 2014.

The subcommittee recommended

- 1. Deleting the word "optional" from Block 18 of Form ST-470, and from Block 4 of Form ST-472.
- 2. Making the wording of Block 4 of Form ST-472 be the same as Blocks 18 and 24 of Form ST-470 with the question in Block 18 to read, "Does the variety contain any biotechnology events?" The term "biotechnology event" was the preferred instead of "transgenic" or "GMO".
- 3. PVPO and ARS should seek advice from OGC counsel regarding the recommended changes and their respective authorities to collect information from applicants.

AMS OGC provided the following advice:

- 1. The word "optional" can be removed from both forms.
- 2. The wording of the two forms can be changed for consistency.
- 3. The term "biotechnology event" can be used in Block 18 of Form ST-470.

- 4. All changes are subject to the Office of Management and Budget's (OMB) approval process.
- 5. PVPC owners cannot be required to submit regulatory status information 6 months prior to PVPC expiration.

ARS OGC provided the following:

- 1. ARS counsel is currently reviewing the list of questions submitted by the subcommittee.
- 2. OGC will prepare a draft statement that ARS can use to inform seed sample requestors and recipients about the presence of biotechnology events in the samples provided and about the regulatory status of such events.
- 3. OGC will recommend that ARS should consult with EPA.

PVP Forms Next Steps

- 1. The ARS National Center for Genetic Resources Preservation (NCGRP) is reviewing Form ST-472 to suggest possible changes that might be useful for the maintenance of voucher samples.
- 2. The subcommittee will reconvene after receiving advice from ARS OGC and suggestions from NCGRP.
- 3. On the basis of the advice received, the subcommittee will prepare final recommendations.
- 4. These recommendations will be presented to the Board at its next meeting.

Neither ARS nor the PVPO has the authority or resources to verify the accuracy of biotechnology event regulatory information. ARS and the PVPO can accept information that is voluntarily provided using the forms/information sheets that were developed by ASTA (these include 1. ASTA GUIDANCE ON COMMUNICATION REGARDING PLANT VARIETY PROTECTION SEED DEPOSITS CONTAINING BIOTECHNOLOGY EVENTS, 2. PVP SEED DEPOSIT DECLARATION: PRESENCE OF EVENT(S) IN PVP SEED DEPOSIT, 3. PLANT VARIETY PROTECTION APPLICANT: COMMITMENT TO PROVIDE INFORMATION TO USDA, and 4. PVP SEED DEPOSIT DECLARATION IN ADVANCE TO PVP EXPIRY) however; neither the PVPO nor the ARS can distribute these forms (the PVPO does provide a link to the ASTA website where these forms will be available). The Board suggested that ASTA move the footnotes and put them on one page, and change "existing" to "enforceable patents and regulatory status of PVP...." – ASTA will be consulted regarding these edits. The seed owners are discussing the option to use materials for research and this may affect the statement under "Declarations In Advance of PVP Certificate Expiry".

Currently when PVP expires – the standard NCGRP process for non-biotechnology seed is to move that sample from NCGRP to the National Plant Germplasm System (NPGS) working collections to increase seed in order to prepare for sample distribution. The Board asked how much seed is increased – this depends on the species and the resources available at each NPGS working collection. The PVPO voucher specimen is 3,000 seeds with 80% germination or better. The NPGS working collections are maintained essentially forever unless there is some difficulty with seed increase, in which case specific accessions can be removed from the collection. This is not likely to happen with PVP voucher specimens. The Board asked who has the liability regarding the registration for those events regulated by EPA - based on advice received by ARS, it's most likely the seed recipient.

NCGRP's holding of PVP seed is different from the issue of the American Type Culture Collection's (ATCC) holding of utility patent seed – those seeds are available from ATCC during the life of the patent but PVP seeds are available from NCGRP only upon PVP expiration, in compliance with PVPO regulations.

OGC explained that PVP forms would fall under the PVP-OMB information collection number, the paperwork reduction act, and that it would probably be best to submit all the changes for PVP forms to OMB at one time. It was suggested that NCGRP talk to the biotechnology event variety owners to discuss the EPA regulatory registration issue.

The next steps will be 1) to hear from ARS OGC and consult with AMS OGC to develop the correct verbiage, 2) the PVP Form Subcommittee would reconvene and make recommendations to the Board, 3) the Board would approve/disapprove of these recommendations, and 4) the PVPO would begin the form change process with OMB.

PVP Marker Subcommittee Update

Dana Rewoldt and Paul Nelson made a presentation about the activity of the joint molecular marker working group. During this year the PVP Board's molecular marker subcommittee 1) conducted a pilot study on expired PVP corn lines, markers and phenotype data; 2) proposed a molecular marker model using genetic distance from reference varieties; and 3) met with ASTA CVIS group to work together on use of markers. The ASTA Corn Variety Identification Subcommittee (CVIS) separately identified a standard set of 3,072 Single Nucleotide Polymorphic (SNP) markers and established 90-95% thresholds during its Essentially Derived Variety (EDV) study for corn.

The PVP Board's subcommittee merged with the ASTA CVIS group to form a Joint Working Group with efforts focused on difficult crops i.e. corn, soybean and lettuce. The Joint group is focused on the technical aspects of applying molecular markers for DUS determination.

The Joint group's short term/immediate needs were: 1) Enabling the use of marker pairwise similarity comparisons when a variety is found as indistinguishable with current PVP data and 2) defining thresholds for distinctness which are probably between the EDV levels of 0.95 – 1.0.

Paul Nelson presented the use of reference varieties in corn varietal distinctness as the "Reference Model" whereby genetic relationship/distance between PVP candidate "subject" varieties and known, pre-determined, "reference" varieties is compared/contrasted. A geographic analogy was used whereby a city's distance from specific reference cities can be used to characterize that city.

The reference model was presented to the UPOV Biochemical and Molecular Techniques and DNA Profiling in Particular Working Party in Korea and will be presented to the UPOV Technical Committee in March 2015.

The reference model data would fit very well into the PVP database framework as an addition to morphology/physiology data. Reference varieties would need to be relevant to the pool of subject varieties under consideration. The reference model has limitations in that data reduction can result in a loss of information and the model will sometimes fail to distinguish between genetically distinct varieties. Most investigative work has been done on corn for markers, procedures, analysis and standards.

The Joint group conducted analyses on expired PVP varieties and company proprietary germplasm using different marker sets of three companies. In general the genetic distance model worked well but needs refinement in that reference varieties and marker sets will need to be determined for each crop. The group worked with the 3,072 EDV marker set as a standard set. The Board commented that the genetic distance model was a good crop specific approach that is based on a set of publicly available markers which are not proprietary and is overall more comprehensive.

The ASTA CVIS established EDV thresholds using the 3,072 SNP set that characterize a variety as being identical when the value is 0.95 and above. In the current study varieties can be considered as distinct when a pair-wise comparison had similarity of less than 0.90 based on the EDV standards. There will always be a need for pair-wise

comparison when the genetic distance model fails. Under the reference model the PVPO would store genetic distance patterns or similarity values for pair-wise comparison rather than raw marker data.

The main features of the reference model are:

- 1. Simplicity in theory and computation.
- 2. Breeders maintain control of DNA fingerprints.
- 3. The U.S. PVPO does not need to store, maintain, or safeguard DNA fingerprints.
- 4. The model fits nicely into the existing PVP framework.
- 5. Genetic similarity coefficients do not replace existing morphological descriptors.

The Board asked if the reference model is being tested in order to be an official procedure. It was indicated that genetic distances are an approved method for genetic comparison and have been published, so this is a good start toward a viable method to complement morphological data in order to describe a new variety.

The long term goals for the reference model are to 1) continue refining distance; 2) assembling genotypes for public sources of reference varieties, 3) assess individual company analyses, 4) select specific reference varieties for each crop, 5) compare cross-company results, and 6) define thresholds for the reference model.

Ongoing reference model efforts by the joint group include:

- 1. Reference variety identification.
- Definition of thresholds for distinctness.
- 3. Determining the usefulness of the reference model across different crops

The existing PVPO molecular marker policy is to permit use of marker data in cases that phenotypic distinction evidence is not conclusive. The PVP Board was informed about the need to resolve PVP submissions when a "phenotypic tie" to other PVP varieties occurs. An approach has been presented to the Board on how to use marker data as supplemental information, which involves providing pair-wise marker comparisons in cases where varieties are showing phenotypic similarity. Furthermore these pair-wise comparisons should meet a scientifically acceptable threshold. The Board made a motion to instruct the PVP Office to accept molecular marker similarities in deciding on distinction between varieties, in cases where the new variety is facing a phenotypic tie. The motion was approved.

The Board commented that marker data can be used to make direct variety comparisons, however morphology should remain the primary means of determining distinctness by the PVPO. The Board asked if marker related data was acceptable

under the PVP Act –PVP doesn't specifically exclude molecular data. The Board discussed the use of molecular markers relative to the UPOV 1991 Convention Article I part (vi) definition of a variety as "can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes" and that marker data is consistent with this definition.

The Board thought that the reference model threshold will be important for the PVPO's determination of distinctness as well as EDV. The threshold will need to be based on published scientific reports on a crop by crop basis. Thresholds are already used in the PVPO for morphological and physiological distinctness data. The Board asked if marker data will hold for different populations of plants that are grown in different ecological locations – those distinctions would be very stable using a good set of robust markers. The best markers are those that show differences among many varieties. The Board suggested developing criteria for markers such as stability, distinction, etc.

The Board asked how the PVPO could certify that the correct markers and methodology was used to generate data –the PVPO currently trust breeder's submission of morphology data so the trust would also exist for marker methodology and data. The Board asked whether for the future instances the reference model would be used routinely or only in the cases of ties. The Board suggested that marker data should be submitted with every application moving forward in order to establish data that can be searched for future applications. However, the requirements and methods for obtaining molecular data would need to be well established so there would be a level playing field for all applicants.

The Board wanted to know if markers were used in the case of a tie – would this "lock the PVPO" – OGC responded that this wouldn't lock the PVPO since applicants would need to provide a variety description using morphology as well as other descriptors. The Board indicated that we should develop verbiage that can be used to describe how the molecular data will be used by the PVPO to describe varieties. The Board recommended that the Molecular Marker Working Group look at the current PVPO policy and modify it as needed and then bring it before the Board. The policy will stay as is until there is a clearer picture.

Introduction to Plant Variety Rights in the European Union

Martin Ekvad made a presentation about the Community Plant Variety Office (CPVO). The CPVO is headquartered in Angers, France; has been operational since 1995; and is the independent European body responsible for the protection of plant variety rights (PVR) in the EU. The CPVO provides breeders with PVR that are enforceable across

the 28 member states of the EU, covering over 500 million people; to date over 50,000 applications have been received for both sexually and asexually propagated species, with approximately 5,500 applications from the U.S. Less than 3% of varieties were protected in more than one EU country until CPVO started. The CPVO is a self-financed EU agency funded by fees charged for services. Martin Ekvad is the President and is responsible for the CPVO's management. The CPVO has a staff of 44, representing 12 nationalities and works in 24 languages with five prominent languages (English, French, German, Dutch and Spanish).

Although the EU system co-exists with the 24 systems of member states, in reality breeders tend to opt for the EU wide PVR protection offered by the CPVO. The CPVO is a full member of UPOV and their system is in line with the UPOV 1991 Act.

If an applicant makes a PVR application to a national office and to the CPVO then the EU PVR prevails. In some instances, it may be better to file in a national office, for example to get a market authorization from a national authority then the CPVO can take over that DUS report. In the EU plant varieties cannot be protected by patents under the European Patent Convention and the EU Directive on patents for biotechnological inventions.

The main features of the CPVO system is that varieties of all botanical genera and species may be protected (the CPVO has received applications for more than 1800 different plant species). The length of the PVP rights under this system is 25 years and 30 for vines, trees and potato varieties. Also, there is provisional protection covering the time from publication of the application until the PVR grant.

The CPVO technical examinations are based on UPOV guidelines. Entrusted examination offices (EOs), which are independent from commercial breeding companies and test the distinctness, uniformity and stability of varieties. The EO tests are prescribed and monitored by the CPVO. The CPVO works with approximately 30 different EOs. There is an independent Quality Audit Service that audits the EOs every three years. One of the most difficult quality requirements for an EO to fulfill is to have a complete reference collection for the varieties that EO examines. Approximately five of the EOs do 80% of the technical examination (France, Netherlands, Germany, United Kingdom, and Spain). The EOs are paid for each examination at the rate of 85% of the costs received from the applicants.

The CPVO can submit reports to any other country's PVP Office on request. The CPVO can request and make decisions based on reports from authorities, EU entrusted examination offices and other UPOV members (if certain quality requirements are

fulfilled). If the CPVO purchases a DUS report, it pays 240 Euros. The CPVO also sells its reports mainly for ornamental and fruit varieties. The CPVO fees are 650 Euros for applying, 1,200 to 2,000 Euros per year/cycle (there is generally one cycle for most species except for trees with up to five cycles) for the DUS test, and 250 Euros for the annual fee to maintain the PVR. The annual fee provides the steady income for the CPVO.

During the 19 years that the CPVO has existed, approximately 57% of applications are submitted for ornamentals, 24% for agricultural species, 13% for vegetables, and 6% for fruits. In the previous 9 months the top five countries of origin for PVR applications are the Netherlands, France, Germany, Denmark, and the United States; non-EU applications are 21% of all submitted. In the previous 10 years, 2,100 to 2,700 PVR applications have been granted each year, which has resulted in the total cumulative PVR grants increasing from 11,500 to approximately 22,500 from 2005 to 2014, respectively.

The number of PVR applications from the U.S. has steadily increased since 1995 – with 433 applications submitted in 2014. The Board asked about the timing of submitting applications – CPVO responded that each species has a defined date when the germplasm must be submitted for testing. Of all the PVR applications from the U.S. since 1995 – most are for ornamental species, followed by agricultural, vegetables, and fruits.

The CPVO looks forward to continue working with the USDA on PVP issues. The CPVO and USDA can review the information requested when filing an application, and through UPOV ensure that application data can be used for applications both to the USDA and the CPVO. The CPVO envisions areas of cooperation in molecular marker applications, and assessing if data can be used to describe varieties for both the U.S. and the EU in a meaningful way. The CPVO and PVPO are proposing a pilot study with lettuce to determine if a grant of PVP would be possible based on each other's final analysis. The CPVO recommends that a representative of the PVPO be present at the UPOV Technical Working Party for Vegetables meeting to be held June 2015 in Angers during which the UPOV lettuce protocol will be discussed.

Overall, the EU PVR system is functioning very well and the CPVO have witnessed a steady climb in applications. The CPVO contributes to 1) efficiencies for applicants, 2) less administration for EU national authorities, 3) close co-operation between CPVO and EU member states on a technical level, and 4) protection at reasonable prices.

The Board asked if there were many EU public sector applicants from the universities and INRA – most applicants are from private seed companies. The Board asked if applicants can file PVP at both an EU member state and at the CPVO– some applicants do file at both but once they have CPVO PVR they cannot use the EU member state protection.

Brainstorming on PVP Outreach

At the December 2013 Board meeting the Board suggested that the PVPO look at several approaches for outreach including:

- Videos showing the PVPO's mission and why PVP is important
- Use social media to promote PVP including Facebook, Twitter, LinkedIn
- Use webinar or online PVP courses
- Reduced fee depending on the applicant size (this is unlikely due to the fee structure in the PVP law)
- Extend PVPO's outreach with better linkage to the seed certification process
- Focus PVP discussion on "why obtain PVP" not "how to obtain PVP"
- Emphasize PVP's place in world food security, sustainability and how varieties can be declared open for public use
- Highlight the fact that PVP germplasm contributed to the public domain germplasm diversity pool (PVP germplasm is publicly available upon PVP expiration)
- Establish linkages with the public relations campaign of IP organizations as a way to promote PVP

The Board suggested that the PVPO considers the idea of PVP education with massive open online video format – MOOC (massive open outline courses) – offered through COURSERA.org such as "How does PVP promote food security and not endanger food security". It was suggested that the PVPO develop discrete three-minute webinars with specific topics (see Daphne Koller on TED talks) such as 1) debunking the myths of GMO, 2) myths of IP monopoly – public use built into the law, and 3) this is what PVP is and this is what PVP is not. It was mentioned that COURSERA has studios to produce these training videos, as does the USDA.

The Board suggested the marketing of PVP to university plant breeders, get the academic deans of these universities to do a one-day session on PVP, and assign an academic credit to it. The Board suggested that wheat and oat breeders from several universities co-teach plant breeding and spend 1-1.5 hours on intellectual property – including PVP. The Board suggested reaching out to more plant breeders. MOOC

offers college credits, and it is free. The Board thought that a video format would be best so that it can be used over and over.

The Board recommended that a subcommittee be formed to develop a PVP outreach plan. The subcommittee would develop outreach ideas, look to increase incoming applications, identify audiences, and develop training/outreach materials. The PVPO receives approximately 80% domestic applications and 20% international applications.

It was also suggested that two different PVP videos be developed: one for the general public, and the other for plant breeders. The Board also discussed the IP site named UNREAL – a platform that discussed the dangers of buying counterfeit goods. The Board made a reference to the Alliance of IP Owners (AIPO) and the International Association for the Protection of Intellectual Property (AIPPI), which also have education programs that the PVPO may consider as it works on approaches to promote PVP.

The PVPO wanted to know what its barriers are with regards to the U.S. PVP system – in that the PTO and the PVP make up the U.S. IP system, and how the Board can help us define the key benefits of the U.S. PVP system.

The Board suggested that there may be opportunities for an entrepreneur to conduct the DUS trials on behalf of a breeder and fulfill the PVP application requirements. The PVPO asked about the possibility of offering an option for DUS trials to be conducted by either a university or other public institution in order to allow more small/medium-sized breeders to file for PVP. The Board suggested that the Ag Experiment Station directors from the Land-grant universities and Ag Extension might be able to conduct DUS trials under a contract. The Board thought that PVPO should further investigate how to offer DUS grow-out services for completing PVP applications, and consult with ASTA on its possible benefits.

The Board wanted to stress that U.S. PVP is not just a niche system, because it is the only U.S. IP system for protecting new plant varieties that has global recognition; plant utility patents do not.

The Board also suggested that the PVPO reaches out to the upcoming chair of ASTA to work with the grass seed industry, and also with the National Association of Plant Breeders (NAPB) to provide a better understanding of the U.S. PVP system. The Board wanted to know how the PVPO's DUS align with the PTO's novelty and non-obviousness, so that there could be a potential interchange between PVP and utility patents with possible dual PVP and utility patent filing—it would be best to understand

what's required for each system. OGC responded that the requirements and concept of utility patents and PVP are very different. The Board suggested avoiding a PVPO versus PTO confrontation – each does what it does well.

The Board noted that we need to consider the fact that each audience will need different outreach information presented to them - for example corn versus vegetable versus grass breeders, versus students. The PVPO will need to convey to each different group why it is important to protect innovation. The Board wanted to know which party in industry and academia the PVPO need to influence the most: the breeder or management – the PVPO believed that it was more important to influence management. The Board suggested having a cohort in each stratum to tell how U.S. PVP helped them as a sort of testimonial. The Board also suggested getting the deans of the 1862 and 1890 colleges involved, as a means of reaching students. The CPVO suggested getting the different associations involved such as vegetable or ornamentals on the issue of intellectual property protection and also looking at key IP universities.

The Board suggested the missing category might be having ambassadors as super users or "go-to" people regarding PVP issues who advocate on behalf of PVP. The Board felt that a subcommittee could assist with PVP outreach but there need to be a clear charge. The Board suggested analyzing incoming PVP applications into categories by crop, and foreign vs. domestic and small-medium-large companies in order to determine who the PVPO is not reaching.

The PVPO presented a possible outreach presentation for use by the Board members that discusses what PVP is, information on the PVPO, and the benefits of PVP, how PVP is granted, how to apply for PVP, and how to contact the PVPO. The Board considered this a good starting point for a subcommittee to further refine. The Board suggested defining the key audiences for outreach, defining the accomplishment parameters, and then targeting those stakeholders. The CPVO revealed that it adopted an external communication policy that might address some of these issues.

Acceptance of DUS reports from other countries PVP Offices

The PVPO can accept other countries' findings for New, Uniform, and Stable; however other countries often conduct a field trial to <u>Distinguish</u> a variety from selected reference varieties with a trial that is based on the minimum number of significant morphological differences. In contrast, the PVPO uses a database search for distinctness based on a complete description of the variety. The PVPO cannot accept other countries' distinctness findings without devaluing future PVPO database searches since 1) the other country's variety description may not be complete enough, 2) they may use of descriptive characteristics not used by the PVPO, and 3) incomplete distinctness

information would leave a "hole" in the PVPO database for that record. Possible solutions to this issue include the idea that third parties conduct DUS trials and then provide information for both the PVPO and the other country to allow both to issue PVP based on that report and variety description.

The Board noted that generally the PVPO wants to issue a PVP certificate and that under the concept of "presumptive issuance" the PVPO could accept DUS reports from other countries as a basis for the New, Distinct, Uniform, and Stable criteria; grant PVP rights; and that this grant could be challenged under the PVP protest (general cancelation) procedure.

The Board asked if there could be contract DUS testing done in the U.S. to fulfill both the PVPO and UPOV DUS requirements. The Board asked whether other countries gather all the PVPO data – and then only report on the distinctive characteristics – the CPVO reported that their EO's collect all the UPOV technical data – but only report on the distinctive traits.

The Board asked if this was an area where molecular markers would help – the PVPO responded that marker data could provide a common language that could be globally recognized.

The Board suggested that perhaps a student clinical component could be added as outreach for the PVPO. The Board mentioned that for ASTA – IP is a top priority. It might be best to recruit university breeders and train them on the collection of PVP data. In addition, it might be useful to get the breeders who work on various crops to develop flowcharts on what data they collect to provide insight to someone who is new to the PVP process. The Board also suggested the concept of experienced PVP filers mentoring inexperienced filers to provide guidance on PVP data collection and application process.

The CPVO suggested that the PVPO could accept the information from another country and then request additional information from the breeder as needed.

The Board also mentioned the development of a PVPO YouTube video with simple images to remind potential applicants that the PVP process focuses on plants, so as to provide less reading and more visual information. The Board commented that video learning has become more common than reading and they suggested reviewing the video of Daphe Koeller.

Seed stakeholder meeting

The PVPO will hold a seed stakeholder meeting with major seed stakeholders (ASTA, AOSCA, AOSA, AASCO, NAPB, PTO, ARS) in Washington, DC in conjunction with the AMS Seed Regulatory and Testing Division. AMS wants to provide the stakeholders with an overview of our two programs; and how we can synergize. The Board members agreed that this is a good approach and may provide feedback to the PVPO.

Issue of the availability of the parents of PVP hybrids at NCGRP

When applicants file PVP for hybrid varieties they must deposit the seed of the hybrid as well as seed of any parents needed to propagate the variety based on section 52(4) of the PVP Act. The seed of the two parent lines used to produce the hybrid variety becomes publically available once the PVP expires under the PVPO's agreement with NCGRP. (NCGRP distributes only the parents of the hybrid so that recipients can reproduce the hybrid variety. NCGRP does not currently have the capacity to produce and distribute hybrid seed.) Seed companies sometimes will use a parent variety to create several other hybrid varieties well beyond the 20+ life of PVP. Breeders of hybrid varieties may be reluctant to file for PVP because of they lose control of the parent with public availability when the PVP expires. The number of hybrid varieties that have been filed for PVP since 1994 is 72.

If NCGRP limited the availability of the parents of PVP hybrids at expiration – this may encourage more PVP applications for hybrid varieties. However, the disadvantage is that there is a potential loss of future publicly available germplasm from these varieties. As a possible compromise NCGRP could retain the parents of hybrid varieties to recreate the hybrid but would not make the parents publicly available upon PVP expiration.

The Board stressed that the basis for U.S. PVP is that a breeder gets a monopoly for a variety for 20+ years and then the variety is publicly available – PVP encourages innovation with an incentive but for a fixed period. The Board suggested that this be looked at from an economic perspective – that by only releasing the hybrid – several varieties are locked up with only the hybrid seed available. Under the CPVO system no seed of any PVR variety is made publicly available.

The Board mentioned that under the Utility patent system – no parents of hybrid seed are required to be deposited – only the hybrid seed is deposited at the ATCC. Some of the Board suggested that the utility patent process doesn't seem to qualify for enablement if the parents of hybrids are not available at the ATCC. The Board commented that perhaps not many hybrid varieties are filed for PVP because there is relatively good protection by the control of the parents – therefore the filing of PVP for

the hybrid is not necessary. It was recommended that applicants get PVP on parents as well as the hybrid varieties.

The Board recommended that the parents of hybrid seed continue to be made publicly available after PVP expiration.

Discussion about using a Website Link Instead of PVP Labels

Under US patent reform, seed companies are allowed to use a "virtual mark" or web page to post their patent numbers (trait and varietal) using a website link on the seed package instead of all inclusive patent numbers. Seed companies like to be efficient in their bag ordering process and try to buy a three to four-year supply and finish laser printing the pertinent variety names, %germ, % foreign matter, intellectual property information, etc. on the bag.

The PVPO asked whether the PVP information need to be printed on a seed package, or be available as a virtual mark web page that could potentially contain 1) trait patents numbers, 2) varietal patents numbers, and 3) PVP numbers all in a central public web location.

The PVP Act indicates in section 127 that "Owners may give notice to the public by physically associating with or affixing to the seed container of a variety, or by fixing to the variety, a label containing either the words "Unauthorized Propagation Prohibited" or the words "Unauthorized Seed Multiplication Prohibited" and after the certificate issues, such additional words as "U.S. Protected Variety"." The PVP Regulations and Rules of Practice also contain similar language in sections 97.140 -97.144.

The advantage of having PVP information via a website link (following the same protocol as the Patent Office) is that it would allow seed sellers to modify (PVP issued vs. pending) information through a website instead of printing new labels. The disadvantages are that the website information would not be as easily accessible as a seed label and require internet time to find the most recent PVP information.

The Board suggested that the knowledge may be presumed if there is a web link and would fulfill the "may give notice" component of the law. The Board made the observation that seed bags might get labeled with "check with this website to determine what intellectual property protection may apply" and this may get put on every seed bag with the burden shifted to the public to determine what IP might apply. The Board also thought that if this were allowed it might impact PVP business if all seed bags are labeled showing whether that variety has IP protection or not.

The Board recommended that the PVPO refers anyone with this question to section 127 of the law and sections 97.140 -97.144 of the regulations – and let them draw their own conclusions. The Board felt that this at the applicant's risk and that the court may need to decide what constitutes "giving notice" with regards to infringement. The greatest risk would be for the person wanting to get infringement damage.

Discussion of PVP information provided on the PVP Website

The PVPO began posting fully scanned PVP certificates in 2002. This includes

- Certificate Face (1 page)
- ST470 application (2 pages)
- Exhibit A (1-10 pages)
- Exhibit B (1-10 pages)
- Exhibit C (3-20 pages)
- Exhibit D (1-15 pages)
- Exhibit E = Ownership (1-2 pages)
- Exhibit F=Seed deposit declaration) (1 page)

The entire certificate and application can exceed 60 pages and color photographs may be included as part of exhibit C or D. The scanned size of 60 pages may exceed 30 MB and the cost of maintaining the server storage space, which requires three servers and several thousand dollars each year. The PVPO showed that the number of visits to the PVPO website varies from 3,000 to 25,000 per month.

Currently the PVPO posts the Certificate face, PVP application (completed ST 470 form) and Exhibits A through E for issued PVP certificates which is approximately 15-50 pages. The PVPO proposes to post only the Certificate Face, the PVP application (completed ST 470 form), and the Examiner's justification for PVP certification (currently not posted). Other information would be available at cost.

The Board suggested that the PVPO provide a subscription service to allow full access versus restricted access with only limited information. The Board commented that the information currently provided by the PVPO is important for infringement issues. The Board also indicated that there must be enough PVP information freely available to serve as examples for those who have never filed for PVP. The Board commented that other countries' PVP Offices do not charge.

The Board also indicated that one of the major problems at the PVPO is financial stability – if maintenance fees are part of this – then it should be changed. The Board asked if a change in maintenance fee would require a statutory or regulatory change –

the PVPO thought that a change to the law would be necessary. The Board considered that minor fee increases for full access, etc. might be a deterrent to obtaining PVP.

The Board recommended that the PVPO continue providing all the information it currently does without restrictions and that perhaps the PVPO could mark all pages with an "Unofficial Copy" watermark for all the information that it posts so that official copies require a fee payment.

PVP 2015-2017 Board and Miscellaneous

The PVPO is seeking nominations for the 2015-2017 PVP Board. The submission of a nomination package (an Application for Committee Membership (AD-755) and resume) should be made by February 6, 2015 and sent to the PVP Office or the Secretary. No member may be appointed for more than three 2-year periods. The term of the present board will expire in May 2015. The first meeting of the new Board will most likely be held in the summer of 2015. The plan for the next Board – is 14 members and 2 alternates – with a slate of 25-30 nominees presented to the Board.

The PVPO asked if the ASTA Chicago meeting is still the best place to hold a Board meeting – the Board agreed that Chicago is probably the best for overall in attendance.

The Board appreciated the participation of Martin Ekvad and the presentation of the CPVO.

The Board meeting was adjourned.

Board Recommendations

- 1) The PVPO should look into a process that can incorporate both the U.S and EU type systems to work in cooperation perhaps via the UPOV International System of Cooperation.
- 2) The PVPO should continue to participate in Seed Association of the Americas (SAA) PVP meetings.
- 3) The PVPO should accept molecular marker similarities in deciding on distinction between varieties, in cases where the new variety is facing a phenotypic tie with existing PVP varieties.
- 4) The Molecular Marker Working Group should review the current PVPO molecular technology policy and modify it as needed and then bring it before the Board.
- 5) The seeds of parents of hybrid PVP varieties should continue to be made publicly available after PVP expiration.

- 6) The PVPO should refer anyone with questions regarding seed package labeling and website labels to section 127 of the PVP Act and sections 97.140 -97.144 of the regulations.
- 7) The PVPO should continue to provide all the information it currently does on its website without restrictions and that perhaps mark all pages with an "Unofficial Copy" watermark for all the information that it posts and that official copies require a fee payment.